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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/700,177

01/29/2001

Ake Lindahl

28069-558 NATL

2132

35437

7590

06/26/2008

MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO

ATTN: PATENT INTAKE CUSTOMER NO. 35437

ONE FINANCIAL CENTER

BOSTON, MA 02111

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/700,177	Applicant(s) LINDAHL ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61,65,81,82,87,90,107-110,114,122 and 143 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 58,61-63,65-68,70,73,76,77,81,82,84,86,87,90,92,95,98-112,114,116-119,121-123,125,126,128-131,133,134,136-139 and 141-143.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 58,62,63,66-68,70,73,76,77,84,86,92,95,98-106,111,112,116-119,121,123,125,126,128-131,133,134,136-139,141 and 142.

DETAILED ACTION

The examiner acknowledges receipt of amendment filed 1/11/08 and 2/22/08, request for extension of time and remarks filed 1/11/08. Claims 58, 61-63, 65-68, 70, 73, 76, 77, 81, 82, 84, 86, 87, 90, 92, 98-112, 114, 116-119, 121-123, 125, 126, 128-131, 133, 134, 136-139 and 141-143 are pending. Claims 58, 62, 63, 66-68, 70, 73, 76, 77, 84, 86, 92, 95, 98-106, 111, 112, 116-119, 121, 123, 125, 126, 128-131, 133, 134, 136-139, 141 and 142 are withdrawn from consideration. No claim is amended.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 61, 65, 81, 82, 87, 90, 107-110, 114, 122 and 143 are rejected under 35

U.S.C. 102(b) as being anticipated by Graham et al. (US 4,814,182).

Graham discloses the formation of polyethylene oxide hydrogel by reacting polyethylene oxide, hexane triol and bis isocyanatocyclohexyl methane (column 2, lines 12-55; Example 1), specific classes of drugs such as antifungal agents are dispersed in the polymerizing monomers or hydrogel (column 3, lines 63 and 64; column 5, lines 53-55). The hydrogel is a homo or copoly (alkylene oxide) and the crosslinking of the polymer is an entanglement cross-linking process that utilizes polymerizing monomers such as glycol dimethacrylate (column 3, lines 3-24). Graham meets the limitations of the claims.

Response to Arguments

3. Applicant's arguments filed 1/11/2008 have been fully considered but they are not persuasive.

4. Applicant argues that Graham does not discuss saturation of the active agent in the hydrogel, but rather teaches preparing the hydrogel in a cast at column 7, lines 11, 12 and 55-57; that the cast hydrogels are then either packed with active agent, i.e. lithium chloride crystals (Graham at column 7, lines 57-60 and column 8, lines 39 and 40); or the hydrogel is swollen in a solution containing an active ingredient, i.e. amino benzoic acid or benzocaine in chloroform (Graham at column 9, lines 28-30 and 66-69); that none of the examples describe a two step process where the active ingredient is added at two different stages and at two different degrees of saturation during preparation of the carrier matrix. The examiner disagrees. The saturated state is formed/obtained when the carrier composition containing the active agent is "subjected to chemical operation(s)" (see page 9, lines 22-32 of the instant specification). Thus, because active agent is "incorporated therewith" (column 1, lines 61 and 62; column 3, lines 25-67; column 4, lines 1-29; column 5, lines 53-57; claim 1) into hydrogel of Graham and the hydrogel is formed by cross-linking/polymerization reaction of monomers, the active agent incorporated therewith is inherently in the saturated state. Since the active agent is incorporated therewith in the hydrogel, the active agent is already present in hydrogel in the casting or moulding stage. The first and second degrees of saturation are inherent to the active agent that is incorporated therewith in the hydrogel. Column 7, lines 11, 12 and 55-57 casts the hydrogel into specific structure which in column 7, lines 57-60 is machined to have a reservoir within which is incorporated the lithium chloride. This reservoir device represents one embodiment of the

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Graham invention. Column 8, lines 39 and 40 also represent another embodiment of Graham in which the lithium chloride is incorporated in hard gelatin capsule, which is inserted into a hollow hydrogel cylinder. It is noted that these examples applicant refers to are embodiments of the Graham invention and those not represent all the embodiments. For example, Graham discloses that "the active substance may be homogeneously or in-homogeneously dispersed throughout the hydrogel" and/or "may also be contained in a reservoir within the hydrogel." These examples applicant refers to represent one embodiment, i.e., incorporating the active agent in a reservoir; also the incorporation of benzocaine by swelling the hydrogel in a solution of benzocaine is yet another embodiment of Graham, and in all, these examples do not render void the disclosure of Graham that the active substance is dispersed in the hydrogel. Graham provides the composition for the polymerization/cross-linking into the hydrogel, disperses the active substance and then allows for the polymerization to take place, thus the steps of providing the monomer mixture containing the active substance and the step during which polymerization takes place is taught by Graham. Therefore, Graham teaches the invention.

No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618